

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 059893-0121 U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5) 10/586,310
INTERNATIONAL APPLICATION NO. PCT/US2005/001469	INTERNATIONAL FILING DATE 1/14/2005	PRIORITY DATE CLAIMED 1/16/2004
TITLE OF INVENTION NPC1L1 (NPC3) AND METHODS OF IDENTIFYING LIGANDS THEREOF		
APPLICANT(S) FOR DO/EO/US Margarita GARCIA-CALVO		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1. <input type="checkbox"/>	This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.	
2. <input checked="" type="checkbox"/>	This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.	
3. <input type="checkbox"/>	This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.	
4. <input type="checkbox"/>	The US has been elected (Article 31).	
5. <input type="checkbox"/>	A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). <input type="checkbox"/> has been communicated by the International Bureau. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US)	
6. <input type="checkbox"/>	An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)) <input type="checkbox"/> is attached hereto. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).	
7. <input type="checkbox"/>	Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <input type="checkbox"/> are attached hereto (required only if not transmitted by the International Bureau). <input type="checkbox"/> have been communicated by the International Bureau. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. <input type="checkbox"/> have not been made and will not be made.	
8. <input type="checkbox"/>	An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).	
9. <input type="checkbox"/>	An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).	
10. <input type="checkbox"/>	An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).	
Items 11 to 20 below concern other document(s) or information included:		
11. <input checked="" type="checkbox"/>	An Information Disclosure Statement under 37 CFR 1.97 and 1.98.	
12. <input type="checkbox"/>	An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.	
13. <input type="checkbox"/>	A preliminary amendment.	
14. <input type="checkbox"/>	An Application Data Sheet under 37 CFR 1.76.	
15. <input type="checkbox"/>	A substitute specification.	
16. <input type="checkbox"/>	A power of attorney and/or change of address letter.	
17. <input type="checkbox"/>	A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825	
18. <input type="checkbox"/>	A second copy of the published international application under 35 U.S.C. 154(d)(4).	
19. <input type="checkbox"/>	A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).	
20. <input type="checkbox"/>	Other items or information:	

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<p>The following fees have been submitted:</p> <table border="1"> <tr> <td>21. <input type="checkbox"/> Basic national fee</td> <td>\$0</td> <td>\$ 0.00</td> </tr> <tr> <td>22. <input type="checkbox"/> Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)</td> <td></td> <td>\$ 0.00</td> </tr> <tr> <td>All other situations</td> <td></td> <td></td> </tr> <tr> <td>23. <input type="checkbox"/> Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority</td> <td></td> <td></td> </tr> <tr> <td>International Search Report prepared and provided to the Office</td> <td></td> <td></td> </tr> <tr> <td>All other situations</td> <td></td> <td>\$ 0.00</td> </tr> <tr> <td colspan="2">TOTAL OF ABOVE 21, 22 and 23 =</td> <td>\$ 0.00</td> </tr> <tr> <td colspan="3"> <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$ for each additional 50 sheets of paper or fraction thereof. </td> </tr> <tr> <td>Total Sheets</td> <td>Extra sheets</td> <td>Number of each additional 50 or fraction thereof (round up to a whole number)</td> <td>RATE</td> </tr> <tr> <td>- =</td> <td>=</td> <td></td> <td>x</td> </tr> <tr> <td colspan="3">Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e))</td> <td>\$ 0.00</td> </tr> <tr> <td>CLAIMS</td> <td>NUMBER FILED</td> <td>NUMBER EXTRA</td> <td>RATE</td> </tr> <tr> <td>Total Claims</td> <td>20</td> <td>- 20 = 0</td> <td>x \$ 50.00</td> </tr> <tr> <td>Independent Claims</td> <td>2</td> <td>- 3 = 0</td> <td>x \$ 200.00</td> </tr> <tr> <td colspan="3">MULTIPLE DEPENDENT CLAIM(S) (if applicable)</td> <td>+ \$ 360.00</td> </tr> <tr> <td colspan="3">TOTAL OF ABOVE CALCULATIONS =</td> <td>\$ 0.00</td> </tr> <tr> <td colspan="3"> <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½. </td> <td>+ \$ 0.00</td> </tr> <tr> <td colspan="3">SUBTOTAL =</td> <td>\$ 0.00</td> </tr> <tr> <td colspan="3">Processing fee of 130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).</td> <td>\$</td> </tr> <tr> <td colspan="3">TOTAL NATIONAL FEE =</td> <td>\$ 0.00</td> </tr> <tr> <td colspan="3">Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). 40.00 per property</td> <td>\$</td> </tr> <tr> <td colspan="3">TOTAL FEES ENCLOSED =</td> <td>\$ 0.00</td> </tr> <tr> <td colspan="3"></td> <td>Amount to be refunded:</td> </tr> <tr> <td colspan="3"></td> <td>charged:</td> </tr> <tr> <td colspan="4"> a. <input type="checkbox"/> A check in the amount of \$ 0.00 to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. <u>19-0741</u> in the amount of \$ 0.00 to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>19-0741</u>. A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charge to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. </td> </tr> <tr> <td colspan="4"> NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. </td> </tr> <tr> <td colspan="4"> SEND ALL CORRESPONDENCE TO: Foley & Lardner LLP Customer Number: 22428 </td> </tr> <tr> <td colspan="4">  SIGNATURE Rouget F. Henschel NAME 39,221 REGISTRATION NUMBER </td> </tr> </table>			21. <input type="checkbox"/> Basic national fee	\$0	\$ 0.00	22. <input type="checkbox"/> Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)		\$ 0.00	All other situations			23. <input type="checkbox"/> Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority			International Search Report prepared and provided to the Office			All other situations		\$ 0.00	TOTAL OF ABOVE 21, 22 and 23 =		\$ 0.00	<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$ for each additional 50 sheets of paper or fraction thereof.			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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Margarita GARCIA-CALVO

Title: NPC1L1 (NPC3) AND
METHODS OF IDENTIFYING
LIGANDS THEREOF

Appl. No.: 10/586,310

International 1/14/2005

Filing Date:

371(c) Date: Unassigned

Examiner: Unassigned

Art Unit: Unassigned

Confirmation Unassigned
Number:

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to
Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56.

STATEMENT

Pursuant to the duty of disclosure under 37 CFR § 1.56, it is requested that the
documents listed on the accompanying Form PTO/SB/08 be considered and made of record in
the above-identified patent application. Other than cited U.S. patents and published
applications, copies of these documents are enclosed. Since the Examiner is believed to have
ready access to the cited U.S. patents and published patent applications, copies of these
documents are not herewith transmitted, but will be provided upon request.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing of a first office action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicant respectfully requests that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

FEES

No office action on the merits of the application has yet been received; accordingly, Applicants believe that no fee is required. If however, any fees are due, the Office may charge such fees to Deposit Account No. 19-0741.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 25- Oct -2006

By 

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 295-4059
Facsimile: (202) 672-5399

Rouget F. Henschel
Attorney for Applicant
Registration No. 39,221

RFHE:kdm

Attachment: PTO/SB/08 and 46 references

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/586,310
Date Submitted: October 25, 2006 (use as many sheets as necessary)				Filing Date	1/14/2005
Sheet	1	of	5	First Named Inventor	Margarita GARCIA-CALVO
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	059893-0121

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		2004/0093629		Altmann <i>et al.</i>	05/13/2004	
		2004/0137467		Altmann <i>et al.</i>	07/15/2004	
		2004/0161838		Altmann <i>et al.</i>	08/19/2004	
		6,426,198		Cartsea <i>et al.</i>	06/30/2002	
		2002/0151536		Davis <i>et al</i>	10/17/2002	
		RE37,721		Rosenblum <i>et al.</i>	05/28/02	
		5,306,817		Thiruvengadam <i>et al.</i>	04/26/1994	
		5,561,227		Thiruvengadam <i>et al.</i>	10/01/1996	
		5,618,707		Homann <i>et al.</i>	04/08/1997	
		5,624,920		McKittrick <i>et al.</i>	04/29/1997	
		5,631,365		Rosenblum <i>et al.</i>	05/20/1997	
		5,656,624		Vaccaro <i>et al.</i>	08/12/1997	
		5,627,176		Kirkup <i>et al.</i>	05/06/1997	
		5,633,246		McKittrick <i>et al.</i>	05/27/1997	
		5,661,145		Davis	08/26/1997	
		5,688,785		Vaccaro	11/18/1997	
		5,688,787		Burnett <i>et al.</i>	11/18/1997	
		5,688,990		Shankar	11/18/1997	
		5,698,548		Dugar <i>et al.</i>	12/16/1997	
		5,728,827		Thiruvengadam <i>et al.</i>	03/17/1998	
		5,739,321		Wu <i>et al.</i>	04/14/1998	
		5,744,467		McKittrick <i>et al.</i>	04/28/1998	
		5,756,470		Yumibe <i>et al.</i>	05/26/1998	
		5,767,115		Rosenblum <i>et al.</i>	06/16/1998	
		5,846,966		Rosenblum <i>et al.</i>	12/08/1998	
		5,856,473		Shankar	01/05/1999	
		5,886,171		Wu <i>et al.</i>	03/23/1999	
		5,919,672		Homann <i>et al.</i>	07/06/1999	
		6,093,812		Thiruvengadam <i>et al.</i>	07/25/2000	

Examiner Signature		Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	
Date Submitted: October 25, 2006				10/586,310	
(use as many sheets as necessary)				Filing Date	
				1/14/2005	
				First Named Inventor	
				Margarita GARCIA-CALVO	
				Group Art Unit	
				Unassigned	
				Examiner Name	
				Unassigned	
Sheet	2	of	5	Attorney Docket Number	059893-0121

U.S. PATENT DOCUMENTS

		U.S. Patent Document			
		6,096,883		Wu <i>et al.</i>	08/01/2000
		6/133,001		Homann <i>et al.</i>	10/17/2000
		6,207,822		Thiruvengadam <i>et al.</i>	03/27/2001
		6,627,757		Fu <i>et al.</i>	09/30/2003
		6,632,933		Altmann <i>et al.</i>	10/14/2003
		6,593,078		Altmann <i>et al.</i>	07/15/2003

UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Application Document		Name of Patentee or Applicant of Cited Document	Filing Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Serial Number	Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
		WIPO	WO2006015365	A1	Mt. Sinai School of Med.	02/09/2006		
		WIPO	WO2005/69900		Merck & Co.	08/04/2005		
		WIPO	WO2004/032716	A2	Massachusetts Institute of Technology	04/22/2004		
		WIPO	WO 01/70974		Takeda Chemical Industries, Ltd.	09/27/2001		
		WIPO	WO 01/57190		HYSEQ, Inc..	08/09/2001		
		WIPO	WO 03/100094		DEVGEN NV	12/04/2003		
		WIPO	WO 00/20623		Schering Corporation	04/13/2000		
		WIPO	WO 00/34240		Schering Corporation	06/15/2000		
		WIPO	WO 00/60107		Schering Corporation	10/12/2000		
		WIPO	WO2004/014947	A1	Aventis Pharma Deutschland GmbH	02/19/2004		

Examiner Signature		Date Considered
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				Examiner Name	Unassigned
				Attorney Docket Number	059893-0121

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
		WIPO	WO 00/63703		Schering Corporation	10/26/2000		
		WIPO	WO 02/079174		Schering Corporation	10/10/2002		
		WIPO	WO 01/75067	A2	HYSEQ, Inc.	10/11/2001		
		WIPO	WO 01/75067 Search Report	A3	HYSEQ, Inc.	10/11/2001		

NON PATENT LITERATURE DOCUMENTS								
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.					T ⁶	
		ERICKSON et al., J. Neuroscience Research, June 2002, pp. 738-744, Vol. 68.						
		ERICKSON et al., J. Inher. Metab. Dis., Feb. 2000, pp. 54-62, Vol. 23.						
		ERICKSON et al., Molecular Reproduction and Development, 2002, pp. 167-173, Vol. 62.,						
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		DAVIES et al., The Journal of Biological Chemistry, April 1, 2005, pp. 12710-12720, Vol. 280, No. 13.						
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		CARSTEA et al., Science, 1997, Vol. 277, pp. 0228-231.						

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Substitute for form 1449B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/586,310
Date Submitted: October 25, 2006 (use as many sheets as necessary)				Filing Date	1/14/2005
Sheet	4	of	5	First Named Inventor	Margarita GARCIA-CALVO
				Group Art Unit	Unassigned
				Examiner Name	Unassigned
				Attorney Docket Number	059893-0121

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		Genbank Sequence Disclosure; Accession No. AF192522.	
		Genbank Sequence Disclosure; Accession No. AF002020.	
		Genbank Sequence Disclosure, Accession No. AK078947.	
		DAVIES <i>et al.</i> , Genomics, 2000, pp. 137-145, Vol. 65, Issue 2.	
		IOANNOU <i>et al.</i> , Mol. Genet. Metab., 2000, pp. 175-181, Vol. 71, No. 1-2.	
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		DAWSON <i>et al.</i> , Curr. Opin. Lipidol, 1999, pp. 315-320, Vol. 10, No. 14.	
		ALLAYEE <i>et al.</i> , Science, 2000, pp. 1709-1711, Vol. 290, No. 5497.	
		BERGE <i>et al.</i> , Science, 2000, pp. 1771-1775, Vol. 290, No. 5497.	
		JOURDHEUIL-RAHMANI <i>et al.</i> , Biochem Biophys Res. Commun., 2002, pp. 390-395, Vol. 292, No. 2.	
		WERDER <i>et al.</i> , Biochemistry, 2001, pp. 11643-11650, Vol. 40, No. 38.	
		Zetia™ Product Information Sheet.	
		Mouse Gene Informatics web page "Gene Detail" of the NPC1L1 gene.	

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